

REMARKS

Applicants appreciate the Examiner's thorough examination of the subject application and request reconsideration of the subject application based on the foregoing amendments and the following remarks.

Claims 34-38, 60-63 and 73-99 are pending in the subject application. Claims 1-33, 39-59 and 64-72 were previously canceled.

Claims 34-38, 60-63 and 73-99 stand rejected under 35 U.S.C. §101 and/or 35 U.S.C. §102.

Claim 35 was amended for clarity.

Claim 36 was amended to address the 35 U.S.C. §101 rejection directed to non-statutory subject matter.

Claim 100 was added so as to further provide that arcuate member is being rotated about a center point or pivot point of the arcuate member and that this pivot point is remote from the adjacent vertebrae.

The amendments to the claims are supported by the originally filed disclosure.

The specification was amended to update the cross-noting paragraph so it now contains the patent number for the previously indicated allowed patent application. The amendment to the specification does not introduce new matter.

35 U.S.C. §101 REJECTIONS

Claims 34-38, 60-63 and 73-99 stand rejected under 35 U.S.C. §101 as provided on pages 2-3 of the above-referenced Office Action. The following separately address the two different grounds for rejection¹².

NON-STATUTORY SUBJECT MATTER

Claims 36 and 37 were rejected under 35 U.S.C. §101 because the claimed invention is directed to non-statutory subject matter. Applicants respectfully traverse.

As indicated above claim 36 was amended so this claim does not affirmatively recite the spine as being a part of the claimed invention. Applicants believe that the areas of rejection have been identified and addressed in the foregoing amendment.

Accordingly, claims 36-37 satisfy the requirements of 35 U.S.C. §101 and, therefore, these claims are allowable.

DOUBLE PATENTING

Claims 34-38, 60-63 and 73-99 are rejected under 35 U.S.C. §101 on the grounds that these claims are clearly claiming the same invention as that of claims 1-61 of prior U.S. Patent No. 6,607,530. Applicants respectfully traverse.

In the issued patent, claims 1-32 are directed to a method for stabilizing adjacent vertebrae of a spine; claims 33-40 are directed to a spinal fixation kit, claim 41 is directed to a

method for fixing two adjacent vertebrae to facilitate bony union thereof; claims 42-53 are directed to another method for stabilizing adjacent vertebrae of a spine; claims 54-57 are directed to another spinal fixation kit and claims 58-61 are directed to yet another spinal fixation kit.

As can be seen from the foregoing none of the claim are directed to a system of an implantable spinal fixation system (claims 34, 35, 73-79), a spinal system (claim 36-37), a spinal fusion kit (claim 38) or a method for stabilizing adjacent segments of a mammalian bone (claims 80-90). As such, it appears that each of these claims are directed to inventions that are clearly not claimed in the identified US patent. Therefore, the same invention is not being claimed in the subject application as was claimed in the previously granted patent. Thus, it is respectfully submitted that claims 34-38, and 73-90 are allowable.

As to claims 60-63, these claims are directed to a method for stabilizing adjacent vertebrae of a spine including, *inter alia*, the steps of: providing a cutting device including a rotating cutting implement having a midpoint; positioning the cutting device proximal a surface of the adjacent vertebrae and so that the rotating cutting implement midpoint is located between the adjacent vertebrae; rotatably cutting a common channel in the adjacent vertebrae with the rotary cutting implement; and inserting a implant into the common channel so that the implant extends between the adjacent vertebrae and through the intervertebral space, the space between the adjacent verterbrae.

In the issued patent, claims 1-32 are directed to methods for stabilizing adjacent vertebrae of a spine and claims 42-53 are directed to another method for stabilizing adjacent vertebrae of a

spine do not contain or recite an steps corresponding to the providing, positioning and rotatably cutting step of the claims of the present invention. Further, claims 58-61 of the issued patent that are directed to yet another spinal fixation kit do not set forth these method steps either.

Therefore, the same invention is not being claimed in the subject application as was claimed in the previously granted patent. Thus, it is respectfully submitted that claims 60-63 are allowable.

As to claims 91-92, these claims are directed to a spinal fixation system that includes, *inter alai*, a plurality of securing members, each securing member being configured so as to be secured respectively in one of the adjacent vertebrae; an arcuate member of a size sufficient to extend between the two adjacent vertebrate; and wherein each of the plurality of securing members is configured so as to mechanically engage separate portions of the arcuate member, thereby securing the arcuate member to each of the adjacent vertebrae.

It first should be recognized that none of the claims of the issued patent are directed to a system much less a spinal fixation system. As such, it first appears that each of claims 91-92 are directed to inventions that are clearly not claimed in the identified US patent. In addition, in the issued patent, claims 33-40 are directed to one spinal fixation kit; claims 54-57 are directed to another spinal fixation kit and claims 58-61 are directed to yet another spinal fixation kit. The spinal fixation kit of claims 33-40 include, *inter alia*, two guide sleeves, each guide sleeve having a long axis and a cross member; claims 54-57 include, *inter alia*, a cutter bracket sub-system; and claims 58-61 include, *inter alia*, a cutting device that includes a cutting element and

a housing where the cutting element is moved from a first position within the housing to a second position outside the housing.

Therefore, the same invention is not being claimed in claims 91-92 of the subject application as was claimed in the previously granted patent. Thus, it is respectfully submitted that claims 91-92 are allowable.

As to claims 93-99, these claims are directed to a method for stabilizing adjacent vertebrae of a mammalian spine, that include, *inter alia*, the steps of: providing a plurality of securing members, each securing member being configured so as to be secured respectively in one of the adjacent vertebrae and an arcuate member of a size sufficient to extend between the adjacent vertebrae; and securing one end portion of the arcuate member to one of the plurality of securing members and securing said one of the plurality of securing members to one of the adjacent vertebrae and securing another end portion of the arcuate member to another of the plurality of securing members and securing said another of the plurality of securing members to the other of the adjacent vertebrae.

In the issued patent, claims 1-32 are directed to methods for stabilizing adjacent vertebrae of a spine and claims 42-53 are directed to another method for stabilizing adjacent vertebrae of a spine. These claims of the issued patent do not contain or recite any steps corresponding to the providing and securing step of claims 93-99 of the present invention.

Therefore, the same invention is not being claimed in the subject application as was claimed in the previously granted patent. Thus, it is respectfully submitted that claims 93-99 are

allowable.

In sum, the claims of the present invention are directed to inventions that were not previously claimed. Also, the claims of the present invention are directed to inventions having elements, features or method steps in their independent claims that are different from the features, elements or method steps of the independent claims of the previously granted patent. Thus, there is *no* correspondence possible between these claims of the present invention and the claims of the previously granted patent. Accordingly, the claims of the present invention and the claims of the previously granted patent do not and cannot read on each other.

Thus, it is submitted that there can be no statutory double patenting. As the claims were rejected solely on statutory double patenting grounds, Applicants have not addressed any possible rejection under non-statutory double patenting.

Accordingly, it is respectfully submitted that claims 34-38, 60-63 and 73-99 satisfy the requirements of 35 U.S.C. §101 and, as such, are in a condition for allowance.

35 U.S.C. §102 REJECTIONS

The Examiner rejected claims 34-38, 60-63 and 73-99 under 35 U.S.C. §102(b) as being anticipated by Lumb [USP 3,426,364]. Applicants respectfully traverse. Because claims were amended in the instant amendment, the following discussion refers to the language of the amended claims. However, only those amended features specifically relied upon to distinguish the claimed invention from the cited prior art shall be considered as being made to overcome the

cited reference.

Lumb describes a prosthetic appliance for replacing one or more vertebrae. Such a prosthetic device includes a y-shaped element 12 that replaces a vertebrae and thus is disposed between two other vertebrae that are adjacent to ends of the y-shaped element. Arches 54 are secured to the y-shaped element and to the two other vertebrae. The arches 54 are secured to the other adjacent vertebrae by means of screws 50. Further, and as shown in the figures of Lumb, the arches are secured to the exterior surfaces of the vertebrae and are not disposed in channels or apertures formed in adjacent vertebrae. Moreover, for the prosthetic device disclosed and taught in Lumb, the body portion 14 also is secured to the vertebrae.

It appears that the Office Action is asserting that element 50 in Lumb corresponds to a part of the arcuate implant. Element 50 is a screw (see col. 3, lines 60-62) and thus is not part of the arch. Therefore element 50 cannot be considered to be part of the arcuate or implant member if one attempts to claim that the arches correspond to the arcuate member or implant of the present invention. Also, nowhere does Lumb disclose or teach forming apertures in each of the adjacent vertebrae in which is received the arcuate member or implant.

The Office Action also asserts that reference numeral 10 corresponds to the arcuate implant. As indicated in Lumb reference numeral 10 “has been employed to designate the prosthetic device in a general way” (see col. 2, lines 48-66 thereof).

Furthermore there is no teaching or disclosure anywhere in Lumb describing stabilizing adjacent vertebrae as the disclosures and teachings in Lumb all include use of a prosthetic device

to replace vertebrae. It can hardly be said that such teaching of replacing vertebrae corresponds to stabilizing adjacent vertebrae when a vertebrae is not being replaced.

Moreover, certain of the method claims of the present invention (claims 80-90) are directed to stabilizing adjacent segments of a bone such as for example a femur. This is not disclosed or taught anywhere in Lumb.

In addition, certain of the method claims of the present invention (claims 60-63) are directed to cutting a channel in the adjacent vertebrae using a rotating element and inserting an implant in the channel. This is not disclosed or taught anywhere in Lumb.

Further, there is no teaching or disclosure anywhere in Lumb of rotating an arcuate member of a size sufficient to extend between the two adjacent vertebrate from a first position to a second position (claims 95-99). In contrast, Lumb merely describes securing curved metal braces 46 to the prosthetic and to the adjacent vertebrae by screws 50 (Fig. 1 thereof) or rigidly securing the arches 54 to the prosthetic(s) and loosely securing the arches to the adjacent vertebrae by screws 50 (Fig. 5 thereof). In the later (Fig. 5), Lumb also teaches that the arches are loosely secured to the adjacent vertebrae so as to provide limited articulate movement as if all connections were made rigid then a large number of vertebrae (natural and artificial) would be fused thus limiting the patient's freedom of movement unduly. See also col. 3, lines 47-62 and col. 4 lines 50-67. In other words, the method of securing the arches to the prosthetics as well as to the adjacent vertebrae essentially precludes rotating these arches from a first position to a second position.

In view of the foregoing, it is clear that Lumb does not describe or disclose the various inventions of the present invention. It also is respectfully submitted that there also is no teaching or suggestion in Lumb for modifying the device, systems and methods described therein so as to yield the method, devices, kits and systems as set forth in the claims. Moreover, any such a modification would necessarily destroy the intended purpose and function and devices described in Lumb as well as changing the intended manner by which such devices and systems would operate.

As provided in MPEP-2131, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegel Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Or stated another way, "The identical invention must be shown in as complete detail as is contained in the ... claims. *Richardson v Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ 2d. 1913, 1920 (Fed. Cir. 1989). Although identify of terminology is not required, the elements must be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990). It is clear from the foregoing remarks that the above identified claims are not anticipated by Lumb.

In deciding the issue of anticipation, the trier of fact must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify *corresponding elements* disclosed in the allegedly anticipating reference (emphasis added, citations in support omitted). *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Company et al.*, 730 F. 2d 1452, 221 USPQ 481,485 (Fed. Cir. 1984). In concluding that the '770 Patent did

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not anticipate the claims, the Federal Circuit in *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Company et al.*, at 221 USPQ 485-486, further provides that:

The '770 patent discloses an entirely different device,
composed of parts distinct from those of the claimed invention, and
operating in a different way to process different materials differently.
Thus, there is no possible question of anticipation by equivalents.
Citations omitted.

It is clear from the foregoing remarks, that the allegedly corresponding elements disclosed in Lumb (*e.g.*, reference numerals 10, 50) do not in fact correspond to the elements of the claimed invention. It also is clear that the system described in Lumb functions and operates in a different manner from that of the claimed invention. As also indicated above, the method disclosed and taught in Lumb for affixing the arches is completely different from that claimed and taught by Applicants for the arcuate member/implant. Thus, there can be no disclosure or teaching in Lumb of Applicants' invention.

As also provided by the Federal circuit in regards to a 35 U.S.C. §103 rejection, such a rejection based upon a modification of a reference that destroys the intent, purpose or function of the invention disclosed in a reference, is not proper and the prima facie case of obviousness cannot be properly made. In short there would be no technological motivation for engaging in the modification or change. To the contrary, there would be a disincentive. *In re Gordon*, 733 F. 2d 900, 221 USPQ 1125 (Fed. Cir. 1984). In the present case it is clear that if the cited reference was modified in the manner suggested by the Examiner it would destroy the intent, purpose or function

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of the prosthetic device/system as taught by the Lumb.

It is respectfully submitted that for the foregoing reasons, claims 34-38, 60-63 and 73-99 are patentable over the cited reference and thus, satisfy the requirements of 35 U.S.C. §102(b).


As such, these claims are allowable.

It is respectfully submitted that the subject application is in a condition for allowance. Early and favorable action is requested.

Applicants believe that additional fees are not required for consideration of the within Response. However, if for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, the Commissioner is hereby authorized and requested to charge Deposit Account No. **04-1105**.

Respectfully submitted,
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